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beginning at the first end and exiting through the second end of the subcutaneous tunnel; inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized; and

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attaching the proximal portion of the hub body to the distal portion of the catheter tube.

#### Remarks

Claims 1-15 are pending in the application. Claims 1-15 stand rejected. Claims 1, 7, 9, 10, 12, 14, and 15 are hereby amended. The Office Action states that Claims 2-6 would be allowable if rewritten in independent form, and Claims 7-13 would be allowable if rewritten to clarify the meaning of the term "second end.". Applicant respectfully traverses the rejections of Claims 1-15.

# Claim Terminology

A proper understanding of the description of the invention and the claims in the application depends upon a proper understanding of the convention adopted and used throughout the application for the relative terms "proximal" and "distal." As used consistently throughout the application, the point of reference for these terms is an area to be catheterized in a patient. Accordingly, the term "proximal" refers to portions of the invention which are nearest the area to be catheterized as the invention is used to catheterize a patient. Conversely, the term "distal" refers to portions of the invention which are farthest from the area to be catheterized as the invention is used to catheterize a patient.

This convention for the terms "proximal" and "distal" is consistently used throughout the application. For example, catheter tube 12 includes a proximal portion 12a and a distal portion 12b as shown in Figure 1 and as described in the specification at page 5, lines 10-11. The "proximal" portion 12a includes tips 14 and 16 which are those portions of the catheter which are inserted into an area to be catheterized in a patient. Similarly, as shown in Figure 2 and as described in the specification at page 5, lines 15-17, an attachable hub 20 includes a first cannula 22 having a proximal portion 22a and a distal portion 22b, and a second cannula 24 having a proximal portion 24a and a distal portion 24b. The "proximal" portions 22a and 24a are those portions of the cannulae which are nearest the insertion tips 14 and 16 of the catheter tube as shown in Figures 1 and 2.

The specification has been amended to modify the last paragraph of the "Detailed Description" section to make this adopted convention even more explicit in the application. The additions to this paragraph do not constitute prohibited new matter under 35 U.S.C. 132(a), however, because the paragraph merely makes explicit that which was already implicit in the application as described above. See MPEP 2163.07.

This distinction between the terms "proximal" and "distal" as used consistently throughout the specification and claims is discussed further below with respect to the rejections of Claims 1, 14, and 15 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,989,213 to Maginot.

## 2. The Claims, as Amended, are Definite Under 35 U.S.C. 112, Second Paragraph

The Office Action rejected Claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action states that it is unclear what is meant by the "the distal portion of the catheter tube exiting through a second end..." Although Applicant believes that the claims as submitted are definite, Claims 1, 7, 9, 10, 12, 14, and 15 have been amended with full reservation of rights. Specifically, each of these claims has been amended to recite forming a subcutaneous tunnel "having a first and second end." Also, each of these claims has been amended to recite "routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through the second end of the subcutaneous tunnel...." Because Claims 2-6 depend from amended Claim 1, Claim 8 depends from amended Claim 7, Claim 11 depends from amended Claim 10, and Claim 13 depends from amended Claim 12, all of the pending claims now include the amended limitations discussed above.

Applicant believes that Claims 1-15, as amended, particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Accordingly, Applicant requests withdrawal of the rejections under 35 U.S.C. 112, second paragraph.

#### 3. Claims 1, 14, and 15, as Amended, are Not Anticipated By Maginot

The Office Action rejects claims 1, 14, and 15 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,989,213 to Maginot. In order for a claim to be anticipated by a reference, the reference must disclose every element recited in the claim. The Office Action states that Maginot discloses "creating a subcutaneous tunnel, where a first end of the subcutaneous tunnel is near the incision near the area to be catheterized," and "routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through a second end of the subcutaneous tunnel...." For the reasons set forth below, Applicant respectfully traverses the rejections.

Claim 1 is directed to a method for inserting a multi-lumen catheter assembly into an area to be catheterized, the multi-lumen catheter assembly having (a) a multi-lumen catheter tube having a distal portion and a proximal portion, and (b) an attachable hub assembly having a hub body with a distal portion and a proximal portion, the method comprising the steps of: making an incision near the area to be catheterized; inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized; creating a subcutaneous tunnel having a first end and a second end, wherein a first end of the subcutaneous tunnel is near the incision near the area to be catheterized; routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through the second end of the subcutaneous tunnel; and attaching the proximal portion of the hub body to the distal portion of the catheter tube.

The method of claim 1 differs from the method disclosed in Maginot in three (3) important respects. First, in the method of claim 1, the catheter tube 12 is placed in the area to be catheterized and then the catheter tube 12 is routed through the subcutaneous tunnel. (The catheter tube is then attached to the hub body in claim 1.) Maginot, however, discloses these steps occurring in the opposite sequence. That is, Maginot discloses that the catheter system 12 is routed through the subcutaneous tunnel and then the the catheter system is placed in the area to be catheterized. See col. 10, ln. 43 – col. 11, ln. 19. As can be seen from the drawings and description in Maginot, it is necessary to route the proximal portion of the catheter system through the subcutaneous tunnel before placing the proximal portion of the catheter system into the area to be catheterized because both the hub body (identified as 42 in Figure 3) and the locking mechanism (referred to as 56 in Figure 3), which locks the working catheter in relation to the guide catheter, are too large to pass through the subcutaneous tunnel.

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Second, in the method of claim 1, it is the <u>distal</u> portion (using the claim terminology of the pending application, the end opposite from the end that is placed in the area to be catheterized) of the catheter tube 12b that is routed through the subcutaneous tunnel. In contrast, Maginot discloses that it is the <u>proximal</u> portion (using the claim terminology of the pending application, the end that is placed in the area to be catheterized) of the catheter system that is routed through the subcutaneous tunnel. <u>See</u> col. 10, ln. 67 – col. 11, ln. 4.

As explained above, the pending application establishes that "the terms 'distal' and 'proximal' are relative terms with respect to a point of reference," and that for the purposes of the application, "the point of reference is the area to be catheterized." The specification, as amended herein, further states that "the term 'proximal' as used herein refers to portions of the catheter which are nearest the area to be catheterized as the catheter is used to catheterize a patient...," and "the term 'distal' as used herein refers to portions of the catheter which are farthest from the area to be catheterized as the catheter is used to catheterize a patient."

Maginot, on the other hand, adopts an opposite convention for these terms. Throughout the Maginot, the term "distal" is used to refer to portions of the catheter system that are nearest to the area to be catheterized, and the term "proximal" is used to refer to portions of the catheter system that are farthest from the area to be catheterized, i.e., nearest to the fluid conveying device. For example, Maginot states that "the catheter system includes a guide catheter 34 having a central guide lumen 36 which extends the entire length thereof (see also FIGS. 6A-6D). The guide lumen 36 defines a *proximal* guide orifice 38 and a *distal* guide orifice 40." Col. 8, ln. 7-11 (emphasis added). Accordingly, as shown in Figures 10 and 11, the *distal* guide orifice 40 is nearest the area being catheterized.

Therefore, by applying the convention that is both implicitly and explicitly established in the pending application, Maginot does not disclose routing a <u>distal</u> portion (the end opposite from the end that is placed in the area to be catheterized) of the catheter system through a subcutaneous tunnel. Rather, Maginot discloses routing the <u>proximal</u> portion (the end that is placed in the area to be catheterized). Indeed, the distal portion of catheter system in Maginot is not routed through the subcutaneous tunnel at all because the hub body (identified as 42 in Figure 3) is permanently attached to the distal portion of the catheter system and the hub body is too large to pass through the subcutaneous tunnel.

The third difference between the method of claim 1 and the method disclosed in Maginot relates to the direction in which the catheter is routed through the subcutaneous tunnel. In claim 1, the distal portion catheter tube 12b is routed through the subcutaneous tunnel <u>beginning at first end of the subcutaneous tunnel</u>, which is the end near the area to be catheterized (The catheter tube is then attached to the hub body in the claimed method.) Maginot, however, discloses that the catheter system 12 is routed through the subcutaneous tunnel <u>beginning at second end of the subcutaneous tunnel</u>, which is the end that is opposite the end of the tunnel that is near the area to be catheterized. (See col.10, ln. 67 – col. 11, ln. 4.)

Based on the foregoing, the rejection of claim 1, as amended, is improper because Maginot does not disclose every element recited in the claim.

Claim 14 is directed to a method for inserting a multi-lumen catheter assembly into an area to be catheterized, the multi-lumen catheter assembly having (a) a multi-lumen catheter tube having a distal portion and a proximal portion, and (b) an attachable hub assembly having (i) a hub body with a distal portion and a proximal portion, the method comprising the steps of: creating a subcutaneous tunnel having a first end and a second end, wherein the first end of the subcutaneous tunnel is near the area to be catheterized; routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through the second end of the subcutaneous tunnel; making an incision near the area to be catheterized; inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized; and attaching the proximal portion of the hub body to the distal portion of the catheter tube.

The method of claim 14 differs from the method disclosed in Maginot in two (2) important respects. First, in the method of claim 14, it is the <u>distal</u> portion (using the claim terminology of the pending application, the end opposite from the end that is placed in the area to be catheterized) of the catheter tube 12b that is routed through the subcutaneous tunnel. In contrast, Maginot discloses that it is the <u>proximal</u> portion (using the claim terminology of the pending application, the end that is placed in the area to be catheterized) of the catheter system that is routed through the subcutaneous tunnel. See col. 10, ln. 67 – col. 11, ln. 4.

The second difference between the method of claim 14 and the method disclosed in Maginot relates to the direction in which the catheter is routed through the subcutaneous tunnel. In claim 14, the distal portion catheter tube 12b is routed through the subcutaneous tunnel

beginning at first end of the subcutaneous tunnel, which is the end near the area to be catheterized (The catheter tube is then attached to the hub body in the claimed method.)

Maginot, however, discloses that the catheter system 12 is routed through the subcutaneous tunnel beginning at second end of the subcutaneous tunnel, which is the end that is opposite the end of the tunnel that is near the area to be catheterized. (See col.10, ln. 67 – col. 11, ln. 4.)

Based on the foregoing, the rejection of claim 14, as amended, is improper because Maginot does not disclose every element recited in the claim.

Claim 15 is directed to a method for inserting a multi-lumen catheter assembly into an area to be catheterized, the multi-lumen catheter assembly having (a) a multi-lumen catheter tube having a distal portion and a proximal portion, and (b) an attachable hub assembly having (i) a hub body with a distal portion and a proximal portion, the method comprising the steps of: creating a subcutaneous tunnel having a first end and a second end, wherein the first end of the subcutaneous tunnel is near the area to be catheterized; making an incision near the area to be catheterized; routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through the second end of the subcutaneous tunnel; inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized; and attaching the proximal portion of the hub body to the distal portion of the catheter tube.

The method of claim 15 differs from the method disclosed in Maginot in two (2) important respects. First, in the method of claim 15, it is the <u>distal</u> portion (using the claim terminology of the pending application, the end opposite from the end that is placed in the area to be catheterized) of the catheter tube 12b that is routed through the subcutaneous tunnel. In contrast, Maginot discloses that it is the <u>proximal</u> portion (using the claim terminology of the pending application, the end that is placed in the area to be catheterized) of the catheter system that is routed through the subcutaneous tunnel. <u>See col. 10</u>, ln. 67 – col. 11, ln. 4.

The second difference between the method of claim 15 and the method disclosed in Maginot relates to the direction in which the catheter is routed through the subcutaneous tunnel. In claim 15, the distal portion catheter tube 12b is routed through the subcutaneous tunnel beginning at first end of the subcutaneous tunnel, which is the end near the area to be catheterized (The catheter tube is then attached to the hub body in the claimed method.)

Maginot, however, discloses that the catheter system 12 is routed through the subcutaneous

tunnel <u>beginning</u> at second end of the subcutaneous tunnel, which is the end that is opposite the end of the tunnel that is near the area to be catheterized. (See col.10, ln. 67 – col. 11, ln. 4.)

Based on the foregoing, the rejection of claim 15, as amended, is improper because Maginot does not disclose every element recited in the claim.

# Conclusion

Applicant believes this case is now in condition for an immediate allowance of Claims 1-15, and such action is respectfully requested. However, if any issue remains unresolved, Applicant's attorney would welcome the opportunity for a telephone interview to expedite allowance and issue.

Respectfully submitted,

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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John S. Wilson et al.

Serial No.: 10/086,033 Examiner: Nicolas, Frederick C.

Filed: February 28, 2002 Art Unit: 3754

Confirmation No.: 5173

For: MULTI-LUMEN CATHETER WITH ATTACHABLE HUB

Commissioner for Patents Washington, DC 20231

#### MARKED UP VERSION SHOWING CHANGES MADE

In the Specification:

The last paragraph of the section titled "Detailed Description of the Preferred Embodiments" is amended as follows:

Although specific embodiments of the present invention have been illustrated and described in detail, it is to be expressly understood that the invention is not limited thereto. The above detailed description of the embodiment is provided for example only and should not be construed as constituting any limitation of the invention. Modifications will be obvious to those skilled in the art, and all modifications that do not depart from the spirit of the invention are intended to be included within the scope of the appended claims. Also, as is known in the art, the terms "distal" and "proximal" are relative terms with respect to a point of reference. For purposes of the foregoing detailed description of the invention and the appended claims, the point of reference is the area to be catheterized. Accordingly, the term "proximal" as used herein refers to portions of the catheter which are nearest the area to be catheterized as the catheter is used to catheterize a patient. Conversely, the term "distal" as used herein refers to portions of the catheter which are farthest from the area to be catheterized as the catheter is used to catheterize a patient.



In the Claims:

1. (Amended) A method for inserting a multi-lumen catheter assembly into an area to be catheterized, the multi-lumen catheter assembly having (a) a multi-lumen catheter tube having a distal portion and a proximal portion, and (b) an attachable hub assembly having a hub body with a distal portion and a proximal portion, the method comprising the steps of:

making an incision near the area to be catheterized;

inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized;

creating a subcutaneous tunnel <u>having a first end and a second end</u>, wherein a first end of the subcutaneous tunnel is near the incision near the area to be catheterized;

routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through [a] the second end of the subcutaneous tunnel; and

attaching the proximal portion of the hub body to the distal portion of the catheter tube.

7. (Amended) A method for inserting a multi-lumen catheter assembly into an area to be catheterized, wherein the multi-lumen catheter assembly is comprised of (a) a multi-lumen catheter tube with a distal portion and a proximal portion, the catheter tube having at least a first lumen and a second lumen, (b) an attachable hub assembly, the hub assembly having a (i) a hub body with a distal portion and a proximal portion, the proximal portion of the hub body being externally threaded, the hub body being formed about a first cannula and a second cannula, each of the cannula having a proximal portion and a distal portion, (ii) a connection cover having a proximal portion and a distal portion cover fitting axially about the distal portion of the catheter tube, the distal portion of the connection cover being internally threaded, and (iii) a compression sleeve, the compression sleeve fitting axially about the distal portion of the catheter tube and the proximal portions of the first and second cannulae, the method comprising the steps of:

making an incision near the area to be catheterized;



inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized;

creating a subcutaneous tunnel <u>having a first end and a second end</u>, wherein [a] the first end of the subcutaneous tunnel is near the incision near the area to be catheterized;

routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through [a] the second end of the subcutaneous tunnel;

attaching the proximal portion of the hub body to the distal portion of the catheter tube,

wherein the step of attaching the hub body to the catheter tube is further comprised of the steps of:

backfitting the connection cover over the distal portion of the catheter tube;

backfitting the compression sleeve over the distal portion of the catheter tube;

inserting the proximal portion of the first cannula into the first lumen of the distal portion of the catheter tube, and inserting the proximal portion of the second cannula into the second lumen of the distal portion of the catheter tube, to create fluid communication between the first cannula and the first lumen and the second cannula and the second lumen;

compressing the connection between the first and second cannulae and the first and second lumens of the catheter tube by sliding the compression sleeve over the proximal portion of the first and second cannulae that have been inserted into the first and second lumens of the distal portion of the catheter tube; and connecting the distal portion of the connection cover to the proximal portion of the hub body by turning the connection cover so that the threaded portion of the connection cover engages the threaded portion of the hub body, such that the catheter tube is securely attached to the hub body.

9. (Amended) A method for inserting a multi-lumen catheter assembly into an area to be catheterized, wherein the multi-lumen catheter assembly is comprised of (a) a multi-lumen catheter tube with a distal portion and a proximal portion, the catheter tube having at least a first lumen and a second lumen, (b) an attachable hub assembly, the hub assembly having a (i) a hub body with a distal portion and a proximal portion, the hub body being formed about a first cannula and a second cannula, each of the cannula having a proximal portion and a distal portion, (ii) a connection cover having a proximal portion and a distal portion, the connection cover fitting axially about the distal portion of the catheter tube, and (iii) a compression sleeve, the compression sleeve fitting axially about the distal portion of the catheter tube and the proximal portions of the first and second cannulae, the first lumen and the first cannula each having a first indicator associated therewith, and the second lumen and the second cannula each having a second indicator associated therewith, the method comprising the steps of:

making an incision near the area to be catheterized;

inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized;

creating a subcutaneous tunnel <u>having a first end and a second end</u>, wherein [a]

the first end of the subcutaneous tunnel is near the incision near the area to be catheterized;

routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through [a] the second end of the subcutaneous tunnel;

attaching the proximal portion of the hub body to the distal portion of the catheter tube,

wherein the step of attaching the hub body to the catheter tube is further comprised of the steps of:

backfitting the connection cover over the distal portion of the catheter tube:

backfitting the compression sleeve over the distal portion of the catheter tube;

matching the first indicator associated with the first lumen with the first



indicator associated with the first cannula, and inserting the proximal portion of the first cannula into the first lumen of the distal portion of the catheter tube, to create fluid communication between the first cannula and the first lumen; and

matching the second indicator associated with the second lumen with the second indicator associated with the second cannula, and inserting the proximal portion of the second cannula into the second lumen of the distal portion of the catheter tube, to create fluid communication between the second cannula and the second lumen;

compressing the connection between the first and second cannulae and the first and second lumens of the catheter tube by sliding the compression sleeve over the proximal portion of the first and second cannulae that have been inserted into the first and second lumens of the distal portion of the catheter tube; and connecting the distal portion of the connection cover to the proximal portion of the hub body, such that the catheter tube is securely attached to the hub body.

10. (Amended) A method for inserting a multi-lumen catheter assembly into an area to be catheterized, wherein the multi-lumen catheter assembly is comprised of (a) a multi-lumen catheter tube with a distal portion and a proximal portion, the catheter tube having a at least a first lumen and a second lumen, (b) an attachable hub assembly, the hub assembly having a (i) a hub body with a distal portion and a proximal portion, the proximal portion of the hub body being externally threaded, the hub body being formed about a first cannula and a second cannula, each of the cannula having a proximal portion and a distal portion, (ii) a connection cover having a proximal portion and a distal portion, the connection cover fitting axially about the distal portion of the catheter tube, the distal portion of the connection cover being internally threaded, the first lumen and the first cannula each having a first indicator associated therewith, and the second lumen and the second cannula each having a second indicator associated therewith, the method comprising the steps of:

making an incision near the area to be catheterized; inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized;

creating a subcutaneous tunnel <u>having a first end and a second end</u>, wherein [a]

the first end of the subcutaneous tunnel is near the incision near the area to be catheterized;

routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through [a] the second end of the subcutaneous tunnel;

attaching the proximal portion of the hub body to the distal portion of the catheter tube,

wherein the step of attaching the hub body to the catheter tube is further comprised of the steps of:

backfitting the connection cover over the distal portion of the catheter tube;

matching the first indicator associated with the first lumen with the first indicator associated with the first cannula, and inserting the proximal portion of the first cannula into the first lumen of the distal portion of the catheter tube, to create fluid communication between the first cannula and the first lumen; and

matching the second indicator associated with the second lumen with the second indicator associated with the second cannula, and inserting the proximal portion of the second cannula into the second lumen of the distal portion of the catheter tube, to create fluid communication between the second cannula and the second lumen;

connecting the distal portion of the connection cover to the proximal portion of the hub body by turning the connection cover so that the threaded portion of the connection cover engages the threaded portion of the hub body, such that the catheter tube is securely attached to the hub body.

12. (Amended) A method for inserting a multi-lumen catheter assembly into an area to be catheterized, wherein the multi-lumen catheter assembly is comprised of (a) a multi-lumen catheter tube with a distal portion and a proximal portion, the catheter tube having at least

a first lumen and a second lumen, (b) an attachable hub assembly, the hub assembly having a (i) a hub body with a distal portion and a proximal portion, the proximal portion of the hub body being externally threaded, the hub body being formed about a first cannula and a second cannula, each of the cannula having a proximal portion and a distal portion, (ii) a connection cover having a proximal portion and a distal portion, the connection cover fitting axially about the distal portion of the catheter tube, the distal portion of the connection cover being internally threaded, and (iii) a compression sleeve, the compression sleeve fitting axially about the distal portion of the catheter tube and the proximal portions of the first and second cannulae, the first lumen and the first cannula each having a first indicator associated therewith, and the second lumen and the second cannula each having a second indicator associated therewith, the method comprising the steps of:

making an incision near the area to be catheterized;

inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized:

creating a subcutaneous tunnel, wherein a first end of the subcutaneous tunnel is near the incision near the area to be catheterized;

routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through a second end of the subcutaneous tunnel;

attaching the proximal portion of the hub body to the distal portion of the catheter tube,

wherein the step of attaching the hub body to the catheter tube is further comprised of the steps of:

backfitting the connection cover over the distal portion of the catheter tube;

backfitting the compression sleeve over the distal portion of the catheter tube;

matching the first indicator associated with the first lumen with the first indicator associated with the first cannula, and inserting the proximal portion of the first cannula into the first lumen of the distal portion of the catheter tube, to create fluid communication between the first cannula and the first lumen; and

matching the second indicator associated with the second lumen with the second indicator associated with the second cannula, and inserting the proximal portion of the second cannula into the second lumen of the distal portion of the catheter tube, to create fluid communication between the second cannula and the second lumen;

compressing the connection between the first and second cannulae and the first and second lumens of the catheter tube by sliding the compression sleeve over the proximal portion of the first and second cannulae that have been inserted into the first and second lumens of the distal portion of the catheter tube; and connecting the distal portion of the connection cover to the proximal portion of the hub body by turning the connection cover so that the threaded portion of the connection cover engages the threaded portion of the hub body, such that the catheter tube is securely attached to the hub body.

14. (Amended) A method for inserting a multi-lumen catheter assembly into an area to be catheterized, the multi-lumen catheter assembly having (a) a multi-lumen catheter tube having a distal portion and a proximal portion, and (b) an attachable hub assembly having (i) a hub body with a distal portion and a proximal portion, the method comprising the steps of:

creating a subcutaneous tunnel <u>having a first end and a second end</u>, wherein [a] the first end of the subcutaneous tunnel is near the area to be catheterized;

routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through [a] the second end of the subcutaneous tunnel;

making an incision near the area to be catheterized;

inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized; and attaching the proximal portion of the hub body to the distal portion of the catheter tube.

15. (Amended) A method for inserting a multi-lumen catheter assembly into an area to be catheterized, the multi-lumen catheter assembly having (a) a multi-lumen catheter tube.

having a distal portion and a proximal portion, and (b) an attachable hub assembly having (i) a hub body with a distal portion and a proximal portion, the method comprising the steps of:

creating a subcutaneous tunnel <u>having a first end and a second end</u>, wherein [a] <u>the</u> first end of the subcutaneous tunnel is near the area to be catheterized;

making an incision near the area to be catheterized;

routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through [a] the second end of the subcutaneous tunnel;

inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized; and

attaching the proximal portion of the hub body to the distal portion of the catheter tube.

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